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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,296	12/22/2005	Peter William Gage	64681(70403)	3685

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EDWARDS ANGELL PALMER & DODGE LLP  
P.O. BOX 55874  
BOSTON, MA 02205

EXAMINER
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CHANDRAKUMAR, NIZAL S

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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08/12/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/562,296	<b>Applicant(s)</b> GAGE ET AL.	
	<b>Examiner</b> NIZAL S. CHANDRAKUMAR	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-168 is/are pending in the application.
- 4a) Of the above claim(s) 3-160 and 164-168 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 161-163 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/22/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1, 2, 161-163 in the reply filed on 06/24/2009 is acknowledged. The traversal is on the ground(s) that there would not be serious burden if all the groups are examined together. This is not found persuasive because of the reasons of record.

The requirement is still deemed proper and is therefore made FINAL.

Claims 3-160, 164-168 withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected inventions, there being no allowable generic or linking claims. Applicant timely traversed the restriction (election) requirement in the reply filed on 06/24/2009.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 and (dependent claim 2 and 3 due to dependency) rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The meaning of terms BODiPy-FL and PrS is vague rendering the full scope of the claim 1 unclear. These terms are found in the specification (see PG PUB paragraph [0018] & [0069] and [0017] & [0018]), however no definition for these terms applicable to the claims is evident.

### ***Claim Rejections - 35 USC § 102***

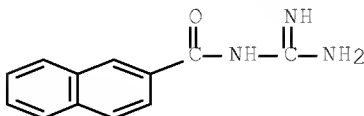
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

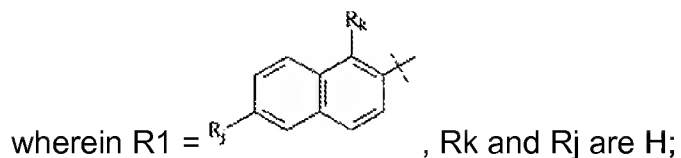
Claims 1, 161 and (dependent claims 2, 162, 163) rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al. Chemical & Pharmaceutical Bulletin (1997), 45(8), 1282-1286.

Yamamoto et al. teach



corresponding to compound of formula of claim 1

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which is also same as compound of claim 161 second page, line 14, 1-naphthoylguanidine.

Note: “[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342,1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

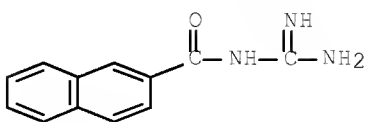
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 161 and (dependent claims 2, 162, 163) rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yamamoto et al. *Chemical & Pharmaceutical Bulletin* (1997), 45(8), 1282-1286.

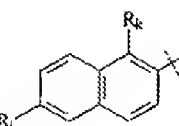
102(b) Reasoning:

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Yamamoto et al. teach



corresponding to compound of formula of claim 1

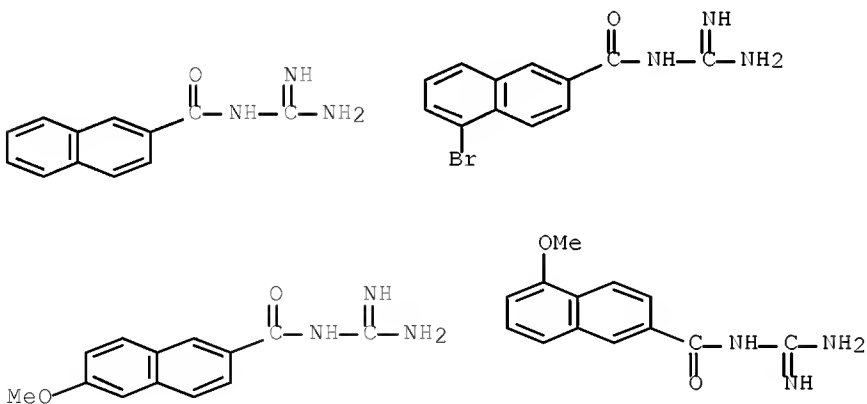
wherein R1 = , Rk and Rj are H.

Which is the same as

compound of claim 161 second page, line 14, 1-naphthoylguanidine.

103 Reasoning:

Yamamoto et al. teach



Thus Yamamoto et al. teach both specific compound and analogs of the instant claims. Yamamoto et al teach that commonly used substituents or their position of attachment to guanidine moiety, are not deleterious to the pharmaceutical use of acylguanidines.

Yamamoto et al. do not teach all the compounds of the instant claims. However, since the specific prior art compound falls within the scope of the instantly claims and is biologically active, it would be obvious to one skilled in the art to make additional

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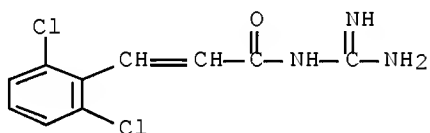
acylguanidines to arrive at compounds within the scope of the Applicant's claims, further because structurally similar compounds are anticipated to possess similar properties.

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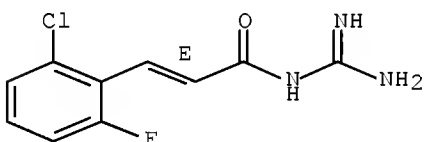
Claims 1, 161 and (dependent claims 2, 162, 163) rejected under 35 U.S.C. 103(a) as being unpatentable over Bream, *Arzneimittel-Forschung* (1975), 25(10), 1477-82.

Instant claims are drawn to acylguanidines wherein the acyl part is varied with large number of groups.

Bream teaches



which is an analog of the instantly claimed compound

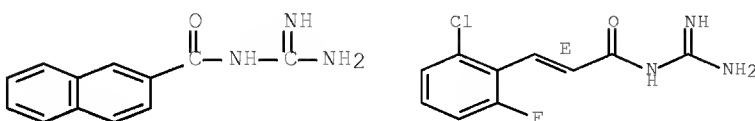


Thus while Bream does not teach all the possible combinations of the instant formula compounds or the specific compounds of claim 161, the different halogens are obvious variants (F Vs Cl) of one another and thus obvious to one of skill in the art. Obviousness based on similarity of structure and functions entails motivation to make the claimed compound in expectation that compounds of similar in structure will have similar properties; therefore, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new compounds.

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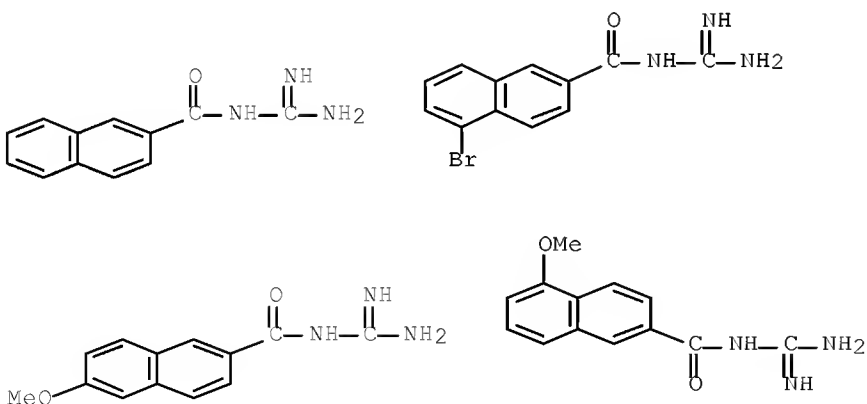
Claims 1, 161 and (dependent claims 2, 162, 163) rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. Chemical & Pharmaceutical Bulletin (1997), 45(8), 1282-1286 and further in view of Bream, Arzneimittel-Forschung (1975), 25(10), 1477-82.

Instant claims are drawn to acylguanidines wherein the acyl part is varied with large number of groups. Examples of compounds of instant claims 1 and 161. .



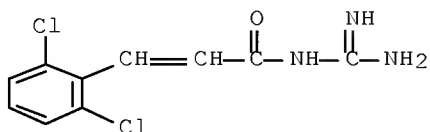
Yamamoto et al. teach

Yamamoto et al. teach



Bream teaches





Yamamoto et al. and Bream do not teach all the compounds of the instant claims. However, it would have been obvious to one of skill in the art would make applicants compounds with reasonable expectation of success because the cited prior arts teach that the pharmaceutical use of acylguanidines is not adversely affected by the substituents on the acyl part. The different substituents are routinely used by one of skill in the art to optimize desired properties. Obviousness based on similarity of structure and functions entails motivation to make the claimed compound in expectation that compounds of similar in structure will have similar properties; therefore, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new compounds.

Prior art not relied upon: Acyl guanidines are well known compounds, See US 7041702, US 6011059, US 5733934, US 5719169, US 5567734, US 4496573.

IDS: Applicant is requested to provide dates for references CE and CF of IDS

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIZAL S. CHANDRAKUMAR whose telephone number is (571)272-6202. The examiner can normally be reached on 8.30 AM - 4.30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571 0272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nizal S Chandrakumar/  
Examiner, Art Unit 1625